REMARKS

A. Introduction

Applicant respectfully requests reconsideration and allowance of this application. Claims 1-40 are pending in the application. Claims 8-19 and 35 have been withdrawn from consideration. Applicant has amended Claims 1, 6, 7, 20, 29 and 37. Applicant's claim amendments are shown on the pages above following the heading AMENDMENTS TO THE CLAIMS.

Applicant submits that this application is now in condition for allowance, and Applicant earnestly requests such action. Below, Applicant addresses each of the Examiner's rejections.

B. 102(e) Rejection of Claims 1, 2, 4-7, 29, 30, 32-34 and 36 Over Hyodoh

In the Office Action mailed February 7, 2006 ("Office Action"), the Examiner rejected Claims 1, 2, 4-7, 29, 30, 32-34 and 36 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0040771A1 to Hyodoh et al. ("Hyodoh"). (Office Action at 2.) Applicant respectfully submits that each of these claims is allowable over Hyodoh.

1. Claim 1

Claim 1 is an independent claim. Applicant has amended Claim 1 to indicate that the means for blocking blood flow past the stent is bio-absorbable. As amended, that claim recites "[a] temporary absorbable venous occlusive stent, comprising: a stent body having a proximal portion and a distal portion; a bio-absorbable material associated with said stent body; and bio-absorbable means for blocking blood flow past said stent when implanted in a vein, at least a portion of said bio-absorbable means disposed at the proximal portion, the distal portion, or at a location between the proximal portion and the distal portion." Hyodoh does not disclose, teach, or suggest this combination of elements.

The Examiner asserts that "[t]he occluders [taught by Hyodoh] can be formed from a variety of bio-absorbable materials, such as polylactic acid (see paragraphs 31, 32, 209, 212, and 213)." (Office Action at 2.) To the contrary, Hyodoh merely discloses that ***the filaments of stents*** used as occluders may be made of biodegradable material. (*Id.* at ¶209) Other components of occluders are not disclosed by Hyodoh as optionally biodegradable.

For example, Hyodoh discloses the use of "an occluding agent" that "may be enclosed within the body." (Hyodoh at ¶229.) Hyodoh states that "any suitable material" may be used as

an occluding agent. (*Id.*) The Examiner has not shown that Hyodoh states that a bio-absorbable material would be suitable for this purpose. Indeed, Hyodoh discloses preferred materials for the occluding agent, including polyester and DACRON, neither of which are characterized by Hyodoh as bio-absorbable. (*Id.*)

Furthermore, Hyodoh discloses the use of "a stretchable jacket" that "may be configured to cover at least a portion of the body." (Hyodoh at ¶230.) As with the occluding agent, Hyodoh states that "any suitable material" may be used for the stretchable jacket. (*Id.*) The Examiner has not shown that Hyodoh states that a bio-absorbable material would be suitable for this purpose. Hyodoh discloses preferred materials for the stretchable jacket, including polyurethane and silicone, which Hyodoh does not characterize as bio-absorbable. (*Id.*)

Hyodoh's stated preference to use non-bioabsorbable materials as occluding agents and stretchable jackets with its bioabsorbable stents is understandable, because it is not a goal of Hyodoh to teach a temporary device. Indeed, Hyodoh discloses the use of bio-absorbable stents not because they are temporary, but rather because the use of bioabsorbable stents allows them to additionally "function as drug or nutrient delivery systems as a result of the material used." (Hyodoh at ¶ 209.) In addition to the non-bioabsorbable occluding agents and stretchable jackets discussed above, Hyodoh discloses a number of additional non-bioabsorbable occluder components, including metal clips (*id.* at ¶ 231) and shape memory wires comprising a nickel-titanium alloy known as nitinol (*id.* at ¶ 220).

In view of these teachings, Hyodoh does not disclose a temporary absorbable venous occlusive stent, comprising a stent body having a proximal portion and a distal portion; a bio-absorbable material associated with said stent body; and bio-absorbable means for blocking blood flow past said stent when implanted in a vein, at least a portion of said bio-absorbable means disposed at the proximal portion, the distal portion, or at a location between the proximal portion and the distal portion, as required by Claim 1 as amended.

Accordingly, Applicant respectfully submits that the rejection of Claim 1 should be withdrawn and that Claim 1 as amended should be allowed.

2. Claims 2 and 4-7

Claims 2 and 4-7 are dependent claims that depend from independent Claim 1. As such, the rejection of these claims under § 102(e) as anticipated by Hyodoh is improper for at least the same reasons provided above for amended Claim 1.

Claims 6-7 also include additional limitations not found in Hyodoh. Specifically, each of these claims recites "a drawstring closure system" for the bio-absorbable means for blocking that is not disclosed by Hyodoh. The Examiner asserts that Hyodoh does disclose this limitation, citing to paragraphs 231 and 235. (Office Action at 2.) Applicant respectfully disagrees.

Paragraph 235 of Hyodoh discusses "loop-defining locations" in a single wire embodiment (shown in Fig. 57B) that is inapplicable to the present application. Indeed, Hyodoh expressly teaches that the filaments in the single wire embodiments should not be made from biodegradable material. (Hyodoh at ¶ 209). Furthermore, Paragraph 235 discloses preferred structures for creating the loop-defining locations that are permanently closed (e.g., crimped metal, welding), and thus that are wholly unlike a drawstring, which may be loosened or tightened to open and close an opening.

Paragraph 231 of Hyodoh discloses embodiments wherein the ends of the stent body may be held together using "any suitable means." (*Id.* at ¶ 231.) The Examiner has not shown that Hyodoh teaches or suggests that a drawstring system is such a suitable system. One preferred embodiment in Paragraph 231 uses a monofilament suture threaded through closed structures or other nearby openings at the end of the stent. (*Id.*) Nowhere does that paragraph disclose or suggest that the suture can be loosened or tightened to open and close an opening, as is the case in a drawstring system. Another preferred embodiment of Paragraph 231 uses metal clips to hold together the ends of the stent body. This suggests that Paragraph 231, like Paragraph 235, contemplates an opening that is permanently held closed. As such, these paragraphs do not disclose the additional limitations recited in Claims 6 and 7.

Accordingly, Applicant respectfully submits that the rejection of Claims 2 and 4-7 should be withdrawn and that Claims 2 and 4-7 should be allowed.

3. Claim 29

Claim 29 is an independent claim. Applicant has amended Claim 29 to indicate that the non-filtering blocking wall is bio-absorbable. As amended, that claim recites "[a] temporary

absorbable stent for substantially completely occluding a vein, comprising: a bioabsorbable stent body having a proximal end and a distal end and a lumen therebetween; a non-filtering, continuous side wall defining the lumen of the body and substantially conformable to the wall of the vein to substantially completely block the flow of blood through the side wall and into the lumen; and a non-filtering bio-absorbable blocking wall disposed on the body at either the proximal end or the distal end of the body, or at a location therebetween, to substantially completely block the flow of blood through the lumen.."

As discussed above in connection with Claim 1, Hyodoh does not disclose a non-filtering bio-absorbable blocking wall disposed on the body at either the proximal end or the distal end of the body, or at a location therebetween, as required by Claim 29. Accordingly, Applicant respectfully submits that the rejection of Claim 29 should be withdrawn and that Claim 29 as amended should be allowed.

4. Claims 30, 32, 33, 34 and 36

Claims 30, 32, 33, 34 and 36 are dependent claims that depend from independent Claim 29. As such, the rejection of these claims under § 102(e) as anticipated by Hyodoh is improper for at least the same reasons provided above for amended Claim 29.

Claim 32 also includes additional limitations not found in Hyodoh. Specifically, Claim 32 recites a non-filtering bio-absorbable blocking wall that comprises "a drawstring closure system." As discussed above in connection with Claims 6 and 7, this limitation is not disclosed by Hyodoh.

Accordingly, Applicant respectfully submits that the rejection of Claims 30, 32, 33, 34 and 36 should be withdrawn and that Claims 30, 32, 33, 34 and 36 should be allowed.

Applicant understands that Claim 35 has been withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species. (Office Action at 2.) Claim 35 is a dependent claim depending from independent Claim 29. Accordingly, Applicant submits that if Claim 29 is found to be in condition for allowance, Claim 35 is likewise in condition for allowance.

C. 103(a) Rejection of Claims 1-5, 20-34 and 36-40 Over Reggie in View of Hyodoh

In the Office Action, the Examiner rejected Claims 1-5, 20-34 and 36-40 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0229366 to

Reggie et al. ("Reggie") in view of Hyodoh. (Office Action at 3.) Applicant respectfully submits that each of these claims is allowable over the applied references.

1. Claim 1

The combination of references applied by the Examiner does not teach each and every limitation of Claim 1. The analysis for Hyodoh is provided above. Reggie discloses a flexible member (element 14) for blocking blood flow that is preferably made from "ePTFE," or "expanded polytetrafluoroethylene," a carbon and fluorine based synthetic polymer that is not characterized by Reggie as bio-absorbable. (Reggie at ¶ 17.) Indeed, the Examiner concedes that Reggie does not disclose the use of bioabsorbable materials (see Office Action at 3). Accordingly, Reggie does not disclose a temporary absorbable venous occlusive stent, comprising a stent body having a proximal portion and a distal portion; a bio-absorbable material associated with said stent body; and bio-absorbable means for blocking blood flow past said stent when implanted in a vein, at least a portion of said bio-absorbable means disposed at the proximal portion, the distal portion, or at a location between the proximal portion and the distal portion, as required by Claim 1 as amended.

Accordingly, the applied references in combination do not disclose each and every limitation of Claim 1, and Applicant respectfully submits that Claim 1 as amended is in condition for allowance.

2. Claims 2-5

Claims 2-5 are dependent claims that depend from independent Claim 1. As such, the rejection of these claims under § 103(a) as unpatentable over Reggie in view of Hyodoh is improper for at least the same reasons provided above for amended Claim 1.

3. Claim 20

Claim 20 is an independent claim. Applicant has amended Claim 20 to indicate that the adjustable closure device is bio-absorbable. As amended, that claim recites "[a] temporary absorbable venous occlusive stent, comprising: a stent body comprising a bio-absorbable material; and an adjustable bio-absorbable closure device associated with said stent body, said adjustable bio-absorbable closure device comprising: an open configuration in which said bio-absorbable closure device permits blood flow past said stent body; and a blocking configuration in which said bio-absorbable closure device forms a wall that blocks blood flow past said stent

body." The combination of Reggie and Hyodoh does not disclose, teach, or suggest this combination of elements.

Specifically, as discussed above in connection with Claim 1, Hyodoh does not disclose an adjustable bio-absorbable closure device associated with the stent body, the adjustable bio-absorbable closure device comprising an open configuration in which the bioabsorbable closure device permits blood flow past the stent body, and a blocking configuration in which the bio-absorbable closure device forms a wall that blocks blood flow past the stent body, as required by Claim 20.

The Examiner asserts that Reggie discloses a closure that is adjustable between an open configuration and a closed configuration that blocks blood flow. (Office Action at 3.) The Examiner concedes that Reggie does not disclose an adjustable closure device that is bio-absorbable, and relies on Hyodoh as disclosing the missing element. (*Id.*) As discussed above, Hyodoh contains no such disclosure.

Accordingly, Applicant respectfully submits that the rejection of Claim 20 should be withdrawn and that Claim 20 as amended should be allowed.

4. Claims 21-27

Claims 21-27 are dependent claims that depend from independent Claim 20. As such, the rejection of these claims under § 103(a) as unpatentable over Reggie in view of Hyodoh is improper for at least the same reasons provided above for amended Claim 20.

Claims 25 and 26 also include additional limitations not found in the combination of Hyodoh and Reggie. Specifically, each of these claims recites "a drawstring closure system" that is not disclosed by the applied references. The Examiner asserts that Hyodoh discloses such a feature, citing to Figure 12 and paragraphs 231, 235, and 338. (Office Action at 4.) Applicant respectfully disagrees.

As discussed above in connection with Claims 6 and 7, Paragraphs 231 and 235 of Hyodoh do not disclose a drawstring closing system for a bio-absorbable closure device that forms a wall that blocks blood flow. Those paragraphs discuss preferred structures for creating permanently closed regions, and thus that are wholly unlike a drawstring, which may be loosened or tightened to open and close an opening.

Paragraph 338 of Hyodoh discusses a retrievable open mesh stent for filter applications. (Hyodoh at ¶¶ 330-361.) The monofilament loop shown in Figure 12 of Hyodoh does not perform the function of blocking blood flow. Indeed, the embodiment of Figure 12 does not include a "blocking configuration in which said bio-absorbable closure device forms a wall that blocks blood flow past said stent body," as required by Claim 20 and, through dependency, Claims 25 and 26.

Nonetheless, the Examiner asserts that the monofilament of Figure 12 in Hyodoh performs the same function as the band (element 20) of Reggie – closing one end of a stent. (Office Action at 4.) The Examiner further asserts that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to include a drawstring system at the closed end of the Reggie stent, as taught by Hyodoh, as this is simply a substitution of functionally equivalent systems." (*Id.*) Applicants respectfully disagree.

The band 20 of Reggie does not serve the function of changing the Reggie stent from an open configuration (allowing blood flow) to a blocking configuration (blocking blood flow). Rather, the band 20 includes a self-sealing opening that "will dilate as a catheter, guidewire or other elongate apparatus is advance [sic, advanced] through the self-sealing opening 21." (Reggie at ¶ 16.) That is, the band 20 opens and closes to allow passage of medical equipment (e.g. a guidewire), not blood.

Furthermore, the band 20 is on the distal side of the Reggie stent. As such, it is difficult to access, and is designed to be self-sealing, preferably formed of a nickel titanium alloy that is superelastic at body temperature. (Reggie at ¶ 16.) In stark contrast, the monofilament of the Figure 12 embodiment of Hyodoh is on the proximal side of the stent, where it is more easily accessed by the surgeon who will be removing the non-permanent filter. (Hyodoh at ¶ 334.)

For at least the above reasons, it would not have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the monofilament of the Hyodoh non-permanent filter for the self-sealing band of the Reggie stent.

Accordingly, Applicant respectfully submits that the rejection of Claims 21-27 should be withdrawn and that Claims 21-27 should be allowed.

5. Claim 28

Claim 28 is a dependent claim that depends from independent Claim 1. As such, the rejection of this claim under § 103(a) as unpatentable over Reggie in view of Hyodoh is improper for at least the same reasons provided above for amended Claim 1. Accordingly, Applicant respectfully submits that the rejection of Claim 28 should be withdrawn and that Claim 28 should be allowed.

6. Claim 29

41. The combination of Reggie and Hyodoh does not disclose, teach, or suggest the combination of elements recited in Claim 29: a temporary absorbable stent for substantially completely occluding a vein, comprising: a bioabsorbable stent body having a proximal end and a distal end and a lumen therebetween; a non-filtering, continuous side wall defining the lumen of the body and substantially conformable to the wall of the vein to substantially completely block the flow of blood through the side wall and into the lumen; and a non-filtering bio-absorbable blocking wall disposed on the body at either the proximal end or the distal end of the body, or at a location therebetween, to substantially completely block the flow of blood through the lumen.

Accordingly, Applicant respectfully submits that the rejection of Claim 29 should be withdrawn and that Claim 29 as amended should be allowed.

7. Claims 30-34 and 36

Claims 30-34 and 36 are dependent claims that depend from independent Claim 29. As such, the rejection of these claims under § 103(a) as unpatentable over Reggie in view of Hyodoh is improper for at least the same reasons provided above for amended Claim 29.

Claims 31 and 32 also include additional limitations not found in the combination of Hyodoh and Reggie. Specifically, Claim 31 recites that the non-filtering bio-absorbable blocking wall "is adjustable between a blocking configuration and a non-blocking configuration." Claim 32 recites that the non-filtering bio-absorbable blocking wall "comprises a drawstring closure system." As discussed above, neither Reggie nor Hyodoh disclose these limitations.

Accordingly, Applicant respectfully submits that the rejection of Claims 30-34 and 36 should be withdrawn and that Claims 30-34 and 36 should be allowed.

8. Claim 37

Claim 37 is an independent claim. Applicant has amended Claim 37 to indicate that the adjustable blocking wall is bio-absorbable. As amended, that claim recites "[a] temporary absorbable stent for substantially completely occluding a vein, comprising: a body having a side wall comprising a bio-absorbable material, the side wall having a having a proximal portion and a distal portion, the side wall defining a lumen extending between the proximal portion and the distal portion, the side wall being substantially conformable to a vein wall; and an adjustable bio-absorbable blocking wall coupled with the side wall and configurable to block blood flow to a degree sufficient to induce clotting and fibrosis at an implantation site of the body." As discussed above, the combination of Reggie and Hyodoh does not disclose, teach, or suggest this combination of elements.

Accordingly, Applicant respectfully submits that the rejection of Claim 37 should be withdrawn and that Claim 37 as amended should be allowed.

9. Claims 38-40

Claims 38-40 are dependent claims that depend from independent Claim 37. As such, the rejection of these claims under § 103(a) as unpatentable over Reggie in view of Hyodoh is improper for at least the same reasons provided above for amended Claim 37.

Claims 39 and 40 also include additional limitations not found in the combination of Hyodoh and Reggie. Specifically, Claim 39 recites that the adjustable bio-absorbable blocking wall "is adjustable between a blocking configuration and a non-blocking configuration." Claim 40 recites that the adjustable bio-absorbable blocking wall "comprises a drawstring closure system." As discussed above, neither Reggie nor Hyodoh disclose these limitations.

Accordingly, Applicant respectfully submits that the rejection of Claims 38-40 should be withdrawn and that Claims 38-40 should be allowed.

10. The Examiner Has Not Identified a Teaching, Suggestion or Motivation to Combine the Applied References

The rejection of Claims 1-5, 20-34 and 36-40 under 35 U.S.C. § 103(a) is also improper because the Examiner has not identified a teaching, suggestion or motivation to combine the teachings of Hyodoh and Reggie. Specifically, the Examiner asserts that it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the Reggie

apparatus to include biodegradable components, as taught by Hyodoh. Applicant respectfully disagrees.

First, the Examiner has failed to show where Reggie provides any disclosure that teaches or suggests that it would be advantageous for the components of the Reggie apparatus to be made from non-permanent materials.

Second, Reggie includes statements that ***teach away*** from using non-permanent components. Specifically, Reggie states:

> As will be appreciated from the above-set-forth description, the embolic device **10** and methods of the present invention may provide several advantages over the prior art. For example, the embolic device **10** of ***the present invention causes rapid or substantially instantaneous occlusion*** of the vessel lumen and does not rely on changes that must occur over time, as may be the case with other approaches like glues and implantable occlusion coils. ... Also, ***the device* 10 *provides permanent occlusion*** of the anatomical conduit and does not tend to recannalize over time as may occur with some other occlusion techniques.

(Reggie at ¶ 22 (emphasis added).)

Third, the Reggie device was developed for a purpose that is not well-suited for the use of present-day biodegradable components. Applicant has submitted evidence in support of this argument pursuant to 37 C.F.R. § 1.132 in the form of a declaration from Michael Mirizzi ("Mirizzi Decl.," attached hereto). Mr. Mirizzi is the Director of Incubation & Research at VNUS Medical Technologies, Inc., assignee of the present patent application. (Mirizzi Decl. ¶ 1.) Mr. Mirizzi has extensive and long-standing experienced with biodegradable materials, their mechanical properties, and their use in stents and other implanted medical devices. (Id. ¶ 1; Ex. 1 (curriculum vitae).) Accordingly, he is qualified to provide facts regarding the understanding of a person of ordinary skill in the art reviewing Reggie and Hyodoh at the time of the invention.

The apparatus and method taught by Reggie were developed in connection with medical applications known as "percutaneous in-situ coronary venous arterialization" or "PICVA," and "percutaneous in-situ coronary artery bypass," or "PICAB." (*See* Reggie at ¶ 3; Mirizzi Decl. at ¶ 2.) PICVA and PICAB are catheter-based technologies for treating heart disease. Each uses a

catheter to transform a segment of the coronary venous system into an arterial conduit. (Mirizzi Decl. at ¶ 3.) In PICVA, a coronary artery is connected to the adjacent vein at one site upstream from the lesion, directing oxygenated blood flow into the vein. The oxygenated blood then travels through the venous system in the reverse direction to perfuse the myocardium. In PICAB, two channels are created between the coronary artery and the adjacent vein, one upstream and the other downstream from the lesion. The blood enters the upstream channel, flows through the isolated vein to bypass the lesion, and re-enters the healthy segments of the artery through the downstream channel. (*Id.* ¶ 3.)

In fact, the Reggie device would not work for the intended PICVA and PICAB applications if the device were constructed using present day bioabsorbable materials. (Mirizzi Decl. at ¶ 4.) In these applications, an occluder is used to block the proximal vein so that arterial blood is not shunted back to the right atrium of the heart. For proper operation, the occluder must have very good vessel wall apposition force so that it does not migrate into the heart under the large arterial pressure acting on the device. (*Id.*) If the entire Reggie device were constructed from present day biodegradable materials, the device would not achieve the radial strength/vessel apposition force necessary to hold the occluder in place under arterial pressure in a manner that provides total flow occlusion and prevents migration of the occluding device in the blood vessel. (*Id.*) All present day biodegradable materials exhibit plastic deformation at significantly lower stress levels than metallic materials. As such, the apposition force for the Reggie device would be orders of magnitude weaker with a biodegradable frame than it would be with the preferred metallic frame taught by Reggie. (*See id.*; Reggie at ¶ 15.)

Furthermore, the PICVA and PICAB applications require the occluding device to quickly route oxygenated blood around the stenosis to perfuse the distal heart tissues. (Mirizzi Decl. at ¶ 5.) As such, the occluding device must do a good job of occluding immediately. Occlusion by an implant device depends on many factors, including how well tissue grows-in to occlude the vessel, and the durability of the occlusion in preventing recanalization. (*Id.*) A fully biodegradable Reggie device would only have a sufficient apposition force to work under arterial pressure if there has been substantial in-growth of tissue connecting the device to the vessel wall. That tissue growth, however, requires time to occur, rendering impossible the quick total occlusion required for the PICVA and PICAB applications in the absence of a strong apposition

force provided by the occluding device. (*Id.*) There is no teaching, or even suggestion, in Reggie that the disclosed occlusion device can provide rapid occlusion when constructed out of present day biodegradable materials. (*Id.*)

For the above reasons, Applicant respectfully submits that it is improper to modify the device of Reggie to include bioabsorbable components on the basis of the Hyodoh reference.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present pending claims. Accordingly, issuance of a Notice of Allowance is respectfully requested.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim that distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to each of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned at (949) 760-0404 to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11 1410.

Respectfully submitted,

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